DRUG UTILIZATION REVIEW BOARD **Meeting Minutes, Open Session** **May 10, 2006**		
DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session EDS/White Lakes Mall Wichita/Kansas City Room Topeka, Kansas May 10, 2006	**Members Present:** R. Kevin Bryant, M.D.; Michael Burke M.D; Ph.D. ; Brenda Schewe, M.D., Kevin Waite, PharmD; Dennis Grauer, Ph.D; Roger Unruh, D.O. **DHPF Staff Present:** Anne Ferguson R. Ph.; Mary Lesperance, R.Ph.; Nialson Lee, R.N.; B.S.N. ;Wanda Pohl **EDS Staff Present: :** Debra Quintanilla, R.N.; Lisa Todd, R.Ph.; Karen KluczyKowki, R.Ph.	**Representatives:** Perry Johnson (3M); Jim McClain; (Astra Zeneca); Jessica Hurtig (Gate); Dale Roof (Takeda); Jim Baumann, (Pfizer); Mark Juhn (Pfizer); Bill Giltner (Pfizer), Mike Cattaneo (Pfizer); Tina Hartman (Healthpoint); Amy Eucyl (Astra Zeneca); Susan Wood (DHPF); Joe Summers (TAP); Todd Houldsworth (OMJ); Nancy Perry (EDS); Bruce Kirby (Genetech); Brady Blaser (Genetech); Mary Truhe (DHPF)
TOPIC	**DISCUSSION**	**DECISION AND/OR ACTION**
I. Call to Order	Dr. Michael Burke, Chair, called the Open Meeting of the Drug Utilization Review board to order at 10 a.m.	
II. Announcements	Anne announced that the Falls in the Elderly Outcomes Assessment that was presented by Jason Crowe (ACS Heritage) at the last meeting had the savings calculated incorrectly. The corrected savings for total drug therapy is $117, 647 and $84,983 for high- risk drug therapy.	
III. Review and Approval of March 8, 2006 Meeting Minutes		• A motion to approve the draft meeting minutes was made by Dr. Unruh and seconded by Dr. Waite. The motion carried unanimously by roll call.

TOPIC	DISCUSSION	DECISION AND/OR ACTION
IV. Old Business **A.** Prior Authorization Unit Report (Revised)	• Deb Q. (Prior Authorization unit) reviewed the additions that were made to the report which included: reason for denials, cost savings, and appeals information. • Dr. Grauer questioned the calculations for the cost savings report. • Deb walked through an example for the Board using Growth Hormone. She explained that it is an estimated cost savings. • Dr. Burke commented on the high number of denials for Protopic® • Deb explained that many of the Elidel® and Protopic® denials are due to not meeting the criteria on the basis of age. • Anne stated that when the Board reviewed these drugs for Prior Authorization (PA) criteria, it was reported that 27% of usage was for beneficiaries under age 2. The high denial rate would reflect this utilization pattern. The criteria was written and approved to reflect package labeling and the FDA health advisory which does not recommend usage for children under age 2. • Deb stated the requests for these drugs in children under 2 has decreased as providers have become aware of the criteria. • Dr Unruh commented about the FDA advisory and recent labeling changes for these drugs. He stated they do not	

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IV. Old Business continued	recommend using the drugs in children under two years of age.	
B. Celebrex® **1**. Update Prior Authorization Criteria **2**. Public Comment (5 Minutes) **3.** DUR Board Recommendations	• Anne reviewed the current PA criteria and outlined the proposed revision. The PA criteria has not been updated since July, 2004 and includes Vioxx® and Bextra®. The proposal was to remove from the criteria: Vioxx, Bextra, the diagnoses of Osteoarthritis, Rheumatoid Arthritis, and high risk of colorectal cancer. • Dr. Juhn and Dr. Cattaneo (Pfizer) presented information about Celebrex®. • Dr. Burke questioned Dr. Juhn about the condition of high risk cancer and whether it was listed as an indication in the package labeling. • Dr. Juhn stated it was not. • Dr. Schewe reminded the Board that they reviewed utilization of Proton Pump Inhibitors (PPI's) shortly after the Cox-2's were marketed. The PPI's utilization did not decrease, but steadily increased. • Dr. Juhn questioned whether DHPF has a system in place to monitor for both Celebrex® and a PPI. • Anne stated not at present.	

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B. Celebrex® continued	• Anne asked Dr. Juhn for comments in regards to the April 2006 Green Sheet article that mentioned a study published in the British Medical Journal in December 2005 that Cox-II's do not provide increased safetly against GI adverse events. • Dr. Juhn responded with comments in regards to a study in 1999 and feels they may be referring to that study. • Anne reviewed the cost study report for NSAID's (calendar year 2005) that was distributed to the Board members. • Dr. Grauer questioned whether there is a way to assess GI risk. There is nothing in the criteria that would allow access to these drugs based on risk of GI bleed. • Dr. Schewe feels we are trying to avoid use for acute pain and long term use for OA and RA would put them at continued risk for GI complications. • Dr. Burke points out that risk would be addressed in bullet number two; any history of GI irritation or bleed. • Dr. Grauer responds that the criteria specifies to list symptoms, but it is not clear on what those symptoms would be for risk. • Dr. Schewe asked the PA unit how many PA's would be denied if you removed RA and OA. • Deb Q. answered that quite a few would be denied.	

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B. Celebrex® continued	• Dr. Schewe has concerns that OA may not be a true diagnosis in all cases, but feels RA should remain on the criteria. • Dr. Burke summarized that the Board has concerns about beneficiaries that will require chronic NSAID use while specific risk factors have not been identified for GI complications. • Anne proposed removal of the PA requirement for Celebrex® if the criteria are to remain the same due to the high percentage of approvals. This would alleviate the burden on the PA unit since a majority are approved. • Dr. Burke suggested we may want to consider adding Celebrex® to the Preferred Drug List (PDL). • Without further discussion, a motion was placed before the Board	• A motion was made by Dr. Schewe to remove the PA requirement for Celebrex® with a 6 month post utilization review and seconded by Dr. Bryant. The motion carried with all voting yes with the exception of Dr. Burke who voted no.

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V. New Business **A.** Pro-DUR **1.** High Dose Alerts-Flonase®, Elastat®, Maxair Autohaler®, Seasonal®, Vitamin B-12 injection a. DUR Board Recommendation	• Anne introduced the topic of Pro-DUR edits and specifically outlined the issue of false high dose alerts. • Lisa Todd (EDS pharmacist) reviewed the report she prepared to identify the drugs hitting this edit falsely. There is a "state field" that can be used to correct this problem. • Dr. Schewe questioned if the state override would allow more than a 31 day supply to be filled. • Karen K. indicated that the early refill edit will not be affected by a change to the high dose alert edit as they are two separate edits. • Dr. Burke pointed out that Miralax had 102 overrides for the high dose alert and would like it to be considered for this policy. • Dr. Burke summarized that drug selection will be based on the number of occurrences of hitting the high dose alert falsely and the limited commercially available package size. • Without further discussion, a motion was placed before the Board.	• A motion was made by Dr. Waite to use the State Override Field to eliminate the false high dose alert on the five drugs recommended by EDS plus Miralax 527 G package and was seconded by Dr. Grauer. The motion carried unanimously by roll call.

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V. New Business continued **2.** Dose Optimization a. DUR Board Recommendation	• Anne introduced the topic of Dose Optimization and reviewed the chart that was supplied to the Board members which identifies drugs to consider for this policy. • Dr. Bryant asked for specifics on how the dose substitution would be encouraged. • Anne explained that the claim can be set to deny, deny with override, or pay and notify. • Dr. Burke is concerned about beneficiaries that need to take multiple dosing for tolerability purposes. • Dr.Grauer feels the pharmacist would need to contact the prescriber before making the change to the dispensed prescription and this would be addressed. • Dr. Waite would like to utilize the point of sale (POS) message system to initiate the policy and not deny the claim at this point. • Anne stated that a newsletter will be published soon to address this issue with these specific drugs. • Dr. Waite recommends implementing the policy in phases. Phase one would be to set the edits to pay and report; then review the data again at a later date to see if there has been an improvement to the number of opportunities. Phase two would be to set the edits to deny the claim.	• A motion was made by Dr. Waite to set the edit for dose optimization at POS to pay and report to the pharmacist for the drugs listed in the report and seconded by Dr. Grauer. Drugs will be added to the policy as they are identified by DHPF and

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V. New Business continued	with no further discussion, a motion was placed before the Board.	approved by the Board. The motion carried unanimously.
B. Update Prior Authorization Criteria for TB Drugs/Diagnosis Codes (Isoniazid, Ethambutol, Pyridoxine, Pyrazinaminde, Aminosalicyclic acid, Ethionamide, Capreomycin Cycloserine) **1.** Update Prior Authorization Criteria/ Diagnosis Code Exclude Edit **2.** Public Comment (5 minutes) **3.** DUR Board Recommendation	• Anne presented information in regards to revising the PA criteria and proposed use of the exclude edit as outlined in the Board's information. • No public comment • With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Bryant to allow the exclude edit at the POS of ICD-9 codes 010-018. Until the exclude edit can be validated as useable, revise the PA as proposed by DHPF. The motion was seconded by Dr. Schewe and carried unanimously by roll call.
C. Nuvigil® (armodafinil) Diagnosis Code Restrictions **1.** Diagnosis Code Restriction Proposal **2.** Public Comment (5 minutes) **3.** DUR Board Recommendation	• Anne presented information on a new drug called Nuvigil®. The DHPF proposal is to include this drug in the policy that covers modafinil. According to the information that is available now, the manufacturer of Nuvigil® will be seeking the same indications as modafinil. ICD-9 codes would be required at the POS as follows: 347 cataplexy/narcolepsy; 780.57 Obstructive sleep apnea/hypopnea syndrome; 307.45 shift work sleep disorder. • No public comment • Some discussion surrounded the addition of these drugs to the PDL. • Anne stated they have not been reviewed by the PDL committee and there are currently no plans for the	

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C. Nuvigil® (armodafinil) Diagnosis Code Restrictions - DUR Board Recommendation continued	• PDL committee to review them. • There were questions regarding PA and this drug. • Anne stated this is not PA criteria, but a policy that requires the diagnosis code at the point of sale. • With no further discussion, a motion was placed before the Board.	• A motion was made by Dr. Bryant to include Nuvigil® (armodafinil) in the same policy as modafinil barring changes to the approved indications in the package labeling and was seconded by Dr. Schewe. The motion carried unanimously by roll call.
D. Discussion/Approval of PDL and Resulting PA Criteria for Non-preferred Drugs **1.** Human Growth Hormone a. PDL Advisory Committee Recommendations b. DHPF Proposal for Preferred Drugs and PA Criteria c. Public Comment (5 minutes)	Updated PDL draft minutes were distributed to the Board members prior to the meeting • Mary reviewed the PDL Advisory Committeee Recommendations that all growth hormone products reviewed were found to be clinically equivalent. • Mary stated that the recommendation from DHPF is for Tev-Tropin® to be the preferred Growth Hormone agent, and PA required for Genotropin®, Humatrope®, Norditropin®, Nutropin®, and Saizen (includes all alternative delivery systems and formulations). Mary briefly reviewed the proposed PA criteria • Mr. Kirby (Genetech) presented information about growth hormone products.	

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D. Discussion/Approval of PDL and Resulting PA Criteria for Non-preferred Drugs continued		
d. Discussion	• Without further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Grauer to accept the proposed PA criteria for the non-preferred growth hormone products and seconded by Dr. Unruh. The motion carried unanimously by roll call.
e. DUR Board Recommendation		
2. Adjunct Antiepileptics a. PDL Advisory Committee Recommendations	• Mary reviewed the PDL Advisory Committee's recommendations that the Adjunct Antiepileptics reviewed could be used clinically interchangeably despite pharmacological differences.	
b. DHPF Proposal for Preferred Drugs and PA Criteria	• Mary stated that the recommendation from the DHPF is for Pregabalin (Lyrica®), Gabapentin (Neurontin®), and Levetiracetam (Keppra®) to be preferred agents, and Zonisamide (Zonegran®) and Tiagabine (Gabitril®) to be non-preferred. The proposed PA criteria was presented.	
c. Public Comment (5 minutes)	• No Public Comment	
d. Discussion	• Dr. Grauer questioned the allowance of a non-preferred agent when a pre-existing or co-morbid condition exits.	

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d. Discussion	• Dr. Burke stated that the PDL Committee discussed this and they felt it should be addressed in the PA criteria due to specific contraindications for these medications.	
e. DUR Board Recommendation	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Schewe to accept the draft PA criteria for the adjunct antiepileptic non-preferred agents and seconded by Dr. Waite. The motion carried unanimously by roll call.
3. Fibric Acid Derivatives a. PDL Advisory Committee Recommendations	• Mary reviewed the PDL Advisory Committee's recommendation that all formulations for fenofibrate are clinically equivalent.	
b. DHPF Proposal for Preferred Drugs and PA Criteria	• Mary stated the recommendation from DHPF is for Fenofribrates Tricor® and Triglide® to be preferred agents, and Antara® and Lofibra® to be non-preferred agents. Gemfibrozil will be non-preferred with no PA required.	
c. Public Comment (5 minutes)	• No public comment	

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3. Fibric Acid Derivatives continued d. Discussion e. DUR Board Recommendation	• With no further Board discussion, a motion was place before the Board.	• A motion was made by Dr. Bryant to accept the proposed draft PA criteria for the fibric acid derivatives and was seconded by Dr. Schewe. The motion carried unanimously by roll call.
4. New Inhaled Corticosteroids Asmanex® a. PDL Advisory Committee Recommendations	• Mary reviewed the PDL Advisory Committee's recommendation that mometasone (Asmanex Twisthaler ®) is clinically equivalent to the other agents in this class. This agent has been added to this class as a preferred drug with no changes made to the PA criteria for the non-preferred agents.	
5. Novel Sleep Agents Rozerem® a. PDL Advisory Committee Recommendation	• Mary reviewed the PDL Advisory Committee's recommendation that Ramelteon (Rozerem®) is not clinically equivalent to the other sedative hypnotics and should be considered for addition to the PDL in its own class as a novel sleep agent. Rozerem® will be the preferred agent in this class and currently there are not any non-preferred agents listed in this class.	

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E. Announcements	• Anne announced the departure of Dr. Bryant and Ms. Kroeger from the DUR Board and thanked them for committing their time and expertise to the DUR Board for the last three years.	
VI. Adjournment	• With no further Board discussion, a motion to adjourn was placed before the Board.	• A motion was made to adjourn the open meeting by Dr. Waite and seconded by Dr. Schewe.The motion carried unanimously by roll call. The open meeting adjourned at 12:10 p.m. The executive session was scheduled during lunch.